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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,548	02/26/2004	Donald W. Landry	30000.2USU1	9484
26941	7590	04/22/2005	EXAMINER	
MANDEL & ADRIANO 55 SOUTH LAKE AVENUE SUITE 710 PASADENA, CA 91101			CHISM, BILLY D	
		ART UNIT		PAPER NUMBER
				1654

DATE MAILED: 04/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/789,548	LANDRY ET AL.	
	Examiner	Art Unit	
	B. Dell Chism	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) is/are allowed.
- 6) Claim(s) 1-13 is/are rejected.
- 7) Claim(s) 1 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10-25-04; 9-21-04; 8-13-04</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

1. This is the first action on the merits, with claims 1-13 pending and under consideration.

Claim Objections

2. Claim 1 is objected to for the following informality: claim 1 contains the acronym "V-1", and an acronym in the first instance of claims should be expanded upon/spelled out with the acronym indicated in parentheses, i.e., vasopressin-1 receptor agonist (V-1 receptor agonist).

The abbreviations can be used thereafter.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-4, 6 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Lindberg et al. (Lysine Vasopressin (LV) In The Treatment Of Refractory Hemodialysis Induced Hypotension (HIH), Kidney International, 1988, Vol. 33, No. 1, page 229). Lindberg et al. teach administering lysine vasopressin to human patients undergoing hemodialysis. Administration reduced the number of hypotensive episodes. Because the same active agent is being administered to the same patients according to the same methods steps in Lindberg et al. as is claimed by Applicant, inherently excess extracellular fluid will be reduced, high blood pressure will be stabilized, interdialytic hypertension will be inhibited, and intradialytic hypotension will be inhibited in Lindberg et al. to the same extent claimed by Applicant.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 5 and 7-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lindberg et al. (cited above). Application of Lindberg et al. is the same as in the above paragraph. Lindberg et al. do not teach the use of the vasopressin agonists recited in instant claims 5 and 7-10, and does not teach the dosages recited in the instant claims 11 and 12. It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to use the vasopressin agonists of instant claims 5 and 7-10 in place of lysine vasopressin in the method of Lindberg et al. because the vasopressin agonists of instant claims 5 and 7-10 are known vasopressin agonists and it is routine to substitute one vasopressin agonist for another while achieving only the expected vasopressin agonist effect. It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to determine all operable and optimal dosages for the method of Lindberg et al. because dosage is an art-recognized result-effective variable which is routinely determined and optimized in the pharmaceutical arts.

Conclusion

7. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to B. Dell Chism, whose telephone number is (571) 272-0962. The

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examiner can normally be reached on M-F 08:30 AM - 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, PhD can be reached on (571) 272-0974.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

B. Dell Chism

A handwritten signature in black ink, appearing to read "B. Dell Chism". The signature is written in a cursive style with a large, open loop on the left side.

PATENT EXAMINER